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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,558	07/13/2005	Richard Frank Tester	08830-0307US1	2680

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EXAMINER	
PALENIK, JEFFREY T	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,558	TESTER ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Palenik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,16,23 and 25* is/are pending in the application.

4a) Of the above claim(s) *6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-12,16,23 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8 dec 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Remarks

The Examiner thanks the Applicants for their timely reply filed on 28 February 2008, in the matter of 10/517,558.

Applicants' election **with traverse** of Group I, claims 1-12, 16, 23 and 25 is acknowledged.

Applicants' request for reconsideration of the restriction (lack of unity) requirement has been fully considered by the Examiner considered but is not persuasive. Applicants traverse the restriction on the grounds that "Groups I and III are linked by the "special technical feature" that … each comprise an active agent and a mucoadhesive carrier for the active agent, the mucoadhesive carrier comprising a β-limit dextrin". Applicants' further allege that USPN 4,780,149 "makes a passing reference to the use of β-limit dextrin in pharmaceutical products".

The Examiner respectfully disagrees with Applicants' position and maintains that the Examples practiced by Kaper et al. (USPN 4,780,149) expressly teach the composition of Group II (claims 17-19) wherein a nutritional product comprises β-limit dextrin. Example 3, in particular, teaches a composition wherein β-limit dextrin is interpreted as being the "main energy source" since the composition comprises 66% β-limit dextrin, by weight.

Per PCT Rule 13.1, the international application shall relate to a group of inventions so linked as to form a single general inventive concept or a "unity of invention" (see MPEP 1850). Per PCT Rule 13.2, said "unity of invention" is fulfilled by defining a special technical feature that is shared amidst the claimed inventions. The Rule further specifies that "[t]he expression "special technical features" shall mean those technical features that define a contribution which

each of the claimed inventions, considered as a whole, makes over the prior art."

Applicants' species election **with traverse** of "buccal-melt product" is also acknowledged. It is further acknowledged that Applicants traversal is on the grounds that "each of these species share the special technical feature of claim 1" and that "bioadhesive pharmaceutical formulations comprising β-limit dextrin as a mucoadhesive carrier, as claimed in claim 1, are novel and inventive over the prior art". Applicants' arguments have been fully considered but they are not persuasive, particularly in light of the fact that the International Preliminary Examination Report (IPER), to which Applicants refer, explicitly states that the invention set forth in the instant claim 1 is neither novel nor inventive.

The Examiner lastly acknowledges the addition of and support for new claims 36 and 37. Based on the recited dependency within said claims, claim 36 would have been considered with Group I and claim 37 would have been considered with Group III. The Examiner has fully considered the support provided by Applicants and respectfully maintains that the claims will not be further considered on the merits. Of particular note is the passage in Applicants' specification which discloses the freeze-dried matrix formulation as an alternative form independent from both the wafer and powder forms (pg. 14, lines 21-27). Given this distinction, had claims 36 and 37 been submitted with Applicants' previous revision of claims, the freeze-dried formulation limitation presented in the new claims would also have been subjected to the same election of species requirement as the buccal-melt product and aerosol powder formulations.

In view of the forgoing, the requirements are deemed proper and are therefore made **FINAL**.

Claims 6, 36 and 37 are withdrawn from further consideration pursuant to 37 CFR

1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Applicants timely traversed the restriction requirement between the compositions and methods.

The remaining claims 1-5, 7-12, 16, 23 and 25 are presented and represent all claims under consideration.

Information Disclosure Statement

An Information Disclosure Statement (IDS), filed 28 February 2008, is acknowledged and has been reviewed.

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the Examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "type" in claim 4 is a relative term which renders the claim indefinite. The term "type" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The addition of the term "type" to an otherwise definite expression (e.g. buccal-melt product) extends the scope of the expression so as to render it indefinite (MPEP §2173.05(b)(E)).

Claim 5 is also rejected since it depends from the rejected claim 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7-12, 16, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaper et al. (EP 0 242 913 A2) in view and Burgoyne et al. (USPN

6,046,185). It should be noted that the EP patent to Kaper et al. as well as Kaper et al. (USPN 4,780,149) are of the same patent family both derive foreign priority from NL 8600937.

The instant claims 1, 2, 23 and 25 are directed to a bioadhesive pharmaceutical formulation comprising an active agent and a mucoadhesive carrier for said agent wherein the carrier is β-limit dextrin (BLD). Claims 2 and 23 both recite limitations to the composition of claim 1 wherein BLD is obtainable by hydrolyzing starch. Such a limitation is interpreted by the Examiner as being a product-by-process limitation, which per MPEP §2113, holds no patentable weight. Claim 25 recites that "a waxy starch" as the source material for the product-by-process limitation of claim 23. Since this is further limiting a limitation which holds no patentable weight, it follows that the limitation of claim 25 also holds no weight. Claim 3 further limits the active agent to a pharmaceutically active agent. The composition is recited as being in the form of a buccal-melt product (claim 4) which is further limited to a wafer (claims 5 and 16) and also recited as a thin-film (claims 7 and 16). Herein, and for the purposes of examination on the merits, the Examiner broadly and reasonably interprets a wafer as being a form of or species of a thin film. Claims 8-10 recite the composition of claim 1 as further comprising at least one carbohydrate in the form of alginate, pectin or either of their derivatives. Claims 11 and 12 recite weight percent limitations of alginate within the composition.

Kaper et al. teach a method of making gum-like confections which use a BLD containing food and pharmaceutical products such as confections having a gum structure in addition to other forms such as tablets and deep-freeze products (claims 8 and 9; col. 4, lines 5-13). BLD is taught as being used as both an adhesive carrier or as both a carrier and a binder (col. 4, lines 13-19). Claim 1 teaches that the composition also includes the polysaccharide α-amylase.

Kaper et al. does not teach the inclusion of pectin, alginate or either of their derivatives as the additional carbohydrate components. Nor is it expressly taught, despite the teaching of "a gum structure", that said structure is in the form of a thin film or wafer.

Burgoyne et al. teach a pharmaceutical composition containing a 6,7-dioxygenated steroid compound in admixture with a pharmaceutically acceptable carrier (col. 127, lines 61-65). Said composition is taught as being administered via mucosal tissue using oral, sublingual, vaginal and intranasal routes, wherein the pharmaceutical composition becomes bioavailable upon administration to a patient (col. 128, lines 6-14). Solid forms of the composition are taught as including powders, granules, tablets, capsules, chewing gum, wafers or the like, as well as multiple inert diluents or edible carriers such as gelatin binders, dextrin excipients, and alginate-based disintegrants (col. 128, lines 37-54).

Burgoyne neither expressly teaches the use of the β-limit form of dextrin nor the percent weight ranges for alginate in the composition.

However, in view of the combined teachings of the prior art, one of ordinary skill in the pharmaceutical or nutritional art, at the time of the invention, would have been motivated to combine an adhesive carrier comprising a dextrin-based compound such as β-limit dextrin with at least one additional carbohydrate and a pharmaceutically active agent in order to achieve the instantly claimed bioadhesive pharmaceutical formulation. Such would have been obvious in the absence of evidence to the contrary since both Kaper and Burgoyne teach mucoadhesive wafer-like structures which comprise pharmaceutically active agents coupled with dextrin-based

carriers and at least one additional carbohydrate component. Chewing gum structures, which are practiced by both inventions, are buccally (e.g. orally) administered compositions which are very well known in the art as having many different forms, particularly a wafer or ribbon form as evidenced by Garbutt (USPN 2,156,810; col. 1, lines 9-12; claim 1).

Therefore, a person of ordinary skill in the art would have a reasonable expectation of success in modifying the solid pharmaceutical dosage form practiced by Burgoyne et al. in view of the β-limit dextrin adhesive carrier compound practiced by Kaper et al., since the combined teachings disclose the instantly claimed bioadhesive pharmaceutical formulation.

Neither reference expressly teaches the percent weight ranges for alginate in the composition, as claimed by the Applicants. Since the values of each parameter with respect to the claimed composition are adjustable, it follows that each is a result-effective parameter that a person having ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill, to adjust the amount of alginate or alginate derivative within the composition particularly in light of its role as disintegrating agent as taught by Burgoyne et al. (col. 128, lines 48-50) in order to best control and/or achieve the desired drug release profile. Optimization of the alginate percentage is further supported in light of the teaching of Burgoyne, wherein said drug is also capable of being optimized by an artisan of ordinary skill in the art (col. 128, lines 21-24). Thus, absent some demonstration of unexpected results from the claimed parameters, optimization of any of these parameters would have been obvious at the time of Applicant's invention.

All claims have been rejected; no claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615